**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION** | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327** |
| **THIS DOCUMENT RELATES ONLY TO:**<br><br>**ETHICON WAVE 2 & 3 CASES** | **JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR A PROTECTIVE ORDER RELIEVING DEFENDANTS OF RESPONDING TO PROVISION IN DEFENDANTS' FACT SHEET REQUIRING PRODUCTION OF DEVICE HISTORY RECORDS**

In response to Defendants' motion, Plaintiffs are unable to dispute that assembling the device history records for each Plaintiff pursuant to the Defendant's Fact Sheet ("DFS") would be inordinately burdensome, or that such evidence has yet to be used at ***a single trial or deposition*** in connection with an individual Plaintiff's case. Nonetheless, Plaintiffs continue to push for this information based on peripheral and meritless arguments.

For example, Plaintiffs argue that the time it took Defendants to assemble a device history record is incompatible with FDA regulations, which require that a device history record be available for inspection "upon four days' notice." But Ethicon does not dispute that it could comply with such a requirement. Rather, Ethicon's point is that collecting and producing ***hundreds*** of these records for litigation would be extremely time-consuming and expensive.

Similarly unavailing is Plaintiffs' argument that Defendants must produce device history records because they contain "the only information available" as to whether a Plaintiff's device conforms to design specifications. As set forth below, Defendants have already produced electronically-searchable documents – such as Corrective and Preventive Actions ("CAPAs"),

medical device reports, adverse event reports, and nonconformance summary reports – that would identify manufacturing issues associated with a particular lot or batch of devices. Indeed, Plaintiffs' experts have previously relied on exactly those types of documents in forming their opinions, as demonstrated by the very exhibits Plaintiffs attach to their brief. Defendants have also made clear that they would provide device history records for any lots or batches with respect to which other documents suggest there was a problem during the manufacturing process.

Defendants concede that they agreed to the DFS provision at the beginning of the litigation when the DFS was crafted and entered by the Court. At the time, however, it was contemplated for use in a much smaller number of cases. Sometimes, changed circumstances call for changed procedures. This is such a case.

For all of these reasons, discussed further below, the Court should enter an order relieving Defendants of producing Plaintiffs' device history records for Wave 2 and any subsequent wave(s), unless a particular plaintiff demonstrates a specific need for this information.

## ARGUMENT

As Defendants explained in their opening brief, the Federal Rules of Civil Procedure demand that the burdens of discovery be proportional to its benefits. *See, e.g.*, *Nicholas v. Wyndham Int'l, Inc.*, 373 F.3d 537, 543 (4th Cir. 2004) ("[A] district court may limit 'the frequency or extent of use of the discovery methods otherwise permitted' under the Federal Rules of Civil Procedure if it concludes that . . . 'the burden or expense of the proposed discovery outweighs its likely benefit.'") (quoting Fed. R. Civ. P. 26(b)(2)). Requiring Ethicon to produce device history records for hundreds of cases does not meet this standard. Although Ethicon has already spent approximately ***2,700 employee hours*** compiling the device history

records for the Plaintiffs in Wave 1, Plaintiffs have yet to use such discovery in any individual plaintiff's case. It would be grossly unfair to force Ethicon to continue providing this extremely burdensome discovery when Plaintiffs have no legitimate use or need for it.

Plaintiff argue in response that: (1) production of the records should not impose an arduous burden on Defendants because they are required to keep such records accessible pursuant to certain FDA regulations (Pls.' Opp'n at 1-3); (2) the device history record "is the only information available to an individual plaintiff" and her experts with respect to whether her particular device was properly manufactured (*id*. at 5-7); and (3) Defendants should not be relieved of this burden because they agreed to the provisions of the DFS (*id*. at 4-5). None of these arguments is compelling.

***First***, Plaintiffs' argument that device history records should be easy to produce because the FDA requires that Ethicon store them in an accessible manner is a red herring. According to Plaintiffs, a manufacturer is required to maintain a device history record for every device it manufactures in such a manner that it could be accessible for review by the FDA "upon four days' notice." (Pls.' Opp'n at 2; *see* Ex. 1 to Pls.' Opp'n at 3-4 (affidavit from Anne Wilson testifying that, in her experience, these "records are required to be reasonably accessible for review by the FDA during the course of FDA inspections, which often are conducted in 4 days"); Ex. 1 to Pls.' Opp'n at 4 ("This information in question is information that should be readily accessible for review by the FDA within a 4 day inspection and therefore should not impose any undue burden to Ethicon to comply with the request.").) Thus, Plaintiffs contend, if the retrieval process is "as arduous" as Defendants claim, Ethicon must not be in compliance with FDA regulations. (Pls.' Opp'n at 3.) Plaintiffs' argument is illogical.

As an initial matter, even if the FDA typically gives just four days' notice to inspect a device history record, that says nothing about how long it would take a manufacturer to collect and produce hundreds of these records. As such, the fact that it has taken Ethicon 2,700 hours to produce the device history records for 200 plaintiffs does not suggest a deficiency in Ethicon's compliance. After all, Ethicon is not arguing that it is unable to make the device history records available for inspection or production, but rather that the burden of doing so for hundreds of plaintiffs in the limited timeframe set by the Court places an undue burden on the Company that outweighs any possible utility of these documents. Therefore, Plaintiffs' reliance on the FDA regulations is completely misplaced.

***Second***, Plaintiffs will not be prejudiced by the absence of a device history record. Plaintiffs argue that the device history records provide "the only information available" about whether a particular device was manufactured according to the device's design specifications. (Pls.' Opp'n at 6.) Plaintiffs thus contend that without this information, it will be "more difficult" to prove their manufacturing and design defect claims at trial. In so arguing, however, Plaintiffs neglect to mention that the documents Defendants have already produced would similarly reveal whether there were any issues with a particular lot or batch. In fact, a simple, computerized search for a lot or batch number in the database of Defendants' produced documents – which include CAPAs, medical device reports, internal analyses of complaint trends, and adverse event reports – would identify documents that address manufacturing issues with respect to that particular lot or batch. Moreover, Defendants have also made significant efforts to collect and produce volumes of nonconformance summary reports for lots manufactured between 1998 through 2014. Thus, Plaintiffs can readily identify whether there were any nonconformances associated with their individual lots. Finally, to the extent a

nonconformance is identified with respect to a particular lot, Defendants have agreed to produce the device history record for that lot. There is simply no need to produce a device history record for ***every*** lot at issue in ***every*** case.

While Plaintiffs cite *Ramirez* to support their argument that the device history record is necessary to determine whether there were problems in the manufacturing process for a particular lot, the evidence they cite from that case tells a different story. (*See* Pls.' Opp'n at 7.) There, the plaintiff's expert relied on internal Ethicon documents other than the device history record to support the plaintiff's claims of design and manufacturing defect. Specifically, as stated in the expert's report, he relied on an internal tracking and trending PowerPoint, as well as issue reports "relating to the batch of mesh that was ultimately used" in the Plaintiff's implant. (*See* Ex. 9 to Pls.' Opp'n at 4 (stating that he relied on a "powerpoint and issue reports relating to the batch of mesh that was ultimately used in Jennifer Ramirez's implant").) Thus, Plaintiffs' contention that they would be unable to prove a manufacturing or design defect without the device history records is belied not only by the extensive discovery already produced, but by their own experts who in fact relied on that other discovery to support their theories of defect.[1]

***Third***, the Court should reject Plaintiffs' rigid argument that Defendants should not be relieved of complying with any requirement of the DFS because they "willingly" agreed to its

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[1] Plaintiffs also argue that relying on the documents already produced is "complicated" because some documents have been "lost or destroyed" in a warehouse fire or are otherwise no longer available. (Pls.' Opp'n at 5 & n.9.) As stated above, however, Defendants have produced adverse event reports, tracking and trending analyses, and other manufacturing records associated with Plaintiffs' lots, minimizing any prejudice to Plaintiffs from this minimal loss of records. Plaintiffs also contend that the loss of these records means that there are fewer available to be produced, "making the burden much less than Defendants are claiming." (*Id.* at 9.) But, as set forth in Ms. Lowe's declaration, there were over 200 unique lots for the 200 plaintiffs in Wave 1 – and only 28 lots corresponded with records that were destroyed in the Secur Archiv fire. (Decl. of Mary Carmel Lowe ¶ 15, Nov. 24, 2015 (Ex. 2 to Defs.' Mot.).) Thus, even though Ethicon did not have to produce those records because they were no longer available, Ethicon still processed 186 device history records for the plaintiffs in Wave 1. (*Id.*)

provisions. (Pls.' Opp'n at 4.) As set forth in Defendants' opening brief, the DFS was negotiated under drastically different parameters – namely, a discovery plan that involved preparing a DFS for only twenty, rather than 200, plaintiffs at a time. In addition, the burdens involved in complying with this particular request were unclear until Defendants actually set out to collect hundreds of device history records in such a short amount of time. As the *Manual for Complex Litigation* notes, an MDL court has the discretion to "revis[e] and refine[]" a discovery plan as the litigation progresses to "ensure that it is operating fairly and effectively." *See Manual for Complex Litigation (Fourth)* §§ 11.31, 11.42 (2004) (initial discovery will often "provide information for further defining and narrowing issues, which may lead to revision and refinement of the discovery plan").[2] Ethicon's experiences in collecting device history records for the Wave 1 plaintiffs makes clear that such "revision and refinement" is appropriate here.

For all of these reasons, Defendants respectfully request that the Court grant their motion for a protective order.

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[2] In response to Defendants' alternative request for cost-shifting, Plaintiffs contend that they "should not be punished" for "Defendant's own document storage practices" that are the real cause of burden here. (Pls.' Opp'n at 9.) For the same reasons explained above, there is no truth to Plaintiffs' suggestion that Defendants' document storage practices must not be in compliance with FDA regulations or are otherwise deficient if producing device history records is too burdensome. It is the sheer number of device history records for the 200 plaintiffs in Wave 2, combined with a limited time period in which to produce them, that creates an undue burden. Notably, while this Court has denied Defendants' requests for cost-shifting in the past (*see* PTO No. 68, Sept. 18, 2013), the instant circumstances fulfill the factors that the Court had previously found wanting. In denying Ethicon's request to shift the costs of producing additional foreign regulatory materials, the Court held that there was "nothing before the [C]ourt to suggest a less burdensome, less expensive, and more convenient source from which Plaintiffs can obtain the regulatory documents." (*Id*. at 10.) Instead, the "Plaintiffs would likely have to approach each individual regulatory body to gather the documents." (*Id*.) By contrast, here, Plaintiffs have materials in hand that would disclose whether any individual lot may have experienced problems in the manufacturing process. Defendants have merely requested that they search that information first, and then seek a device history record for any lots with documented issues.

## CONCLUSION

For the foregoing reasons and those set forth in their opening brief, Defendants respectfully request that the Court enter a protective order relieving Ethicon of responding to the inquiry on the Defendant's Fact Sheet concerning device history records for Wave 2 and subsequent waves of cases until a particular plaintiff demonstrates a need for such information.

ETHICON, INC., ETHICON LLC AND
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*/s/ David B. Thomas*

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## CERTIFICATE OF SERVICE

I, David B. Thomas, certify that on December 11, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

*/s/ David B. Thomas*

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